



September 4, 2020

National Freedom of Information Officer
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW (2822T)
Washington, DC 20460
(202) 566-1667

BY FOIA ONLINE AND BY EMAIL: hq.foia@epa.gov

Re: FOIA Request Re: EPA Communication on Ethylene Oxide IRIS Cancer Risk Value and TCEQ “Dose-Response Assessment”

Dear National Freedom of Information Officer:

On behalf of the Sierra Club, we request that the United States Environmental Protection Agency (“EPA”) provide copies of the records described below pursuant to the Freedom of Information Act (“FOIA”), 5 U.S.C. § 552 et seq., and the EPA regulations at 40 C.F.R. § 2.100, et seq. Sierra Club requests a public interest fee waiver for this FOIA request.

First, please provide any and all documents and communications, subsequent to July 1, 2019, regarding or relating to:

- The Texas Commission on Environmental Quality (“TCEQ”) proposed, revised, or final Ethylene Oxide Carcinogenic Dose-Response Development Support Document (“DSD”);¹
- TCEQ’s response to public comment;²
- TCEQ’s peer review of the DSD;³ or
- TCEQ’s response to peer review comments.⁴

¹ TCEQ, Ethylene Oxide Carcinogenic Dose-Response Assessment Development Support Document (May 15, 2020),

<https://www.tceq.texas.gov/assets/public/implementation/tox/dsd/final/eto.pdf>.

² TCEQ, Response to Public Comments Received on the 2019 Ethylene Oxide Draft Development Support Document (Jan. 31, 2020),

<https://www.tceq.texas.gov/assets/public/implementation/tox/dsd/comments/eto/rtc%20public%20comments.pdf>.

³ University of Cincinnati, Risk Science Center, Final Report for Letter Peer Review of Ethylene Oxide Carcinogenic Dose-Response Assessment Development Support Document, Contract No. 582-19-91305, Work Order No. 582-19-91305-01 (PCR 11740) (Apr. 30, 2020),

https://www.tceq.texas.gov/assets/public/implementation/tox/peer_review/eto.pdf.

⁴ TCEQ, Response to External Peer Review Comments Received on the Ethylene Oxide Development Support Document (May 15, 2020),

<https://www.tceq.texas.gov/assets/public/implementation/tox/dsd/comments/eto/rtc%20peer%20review.pdf>.

Second, we request copies of any and all records of information (including communications), subsequent to July 1, 2019, in the possession of EPA's Office of the Administrator (Immediate Office), Office of Research and Development (including but not limited to the Integrated Risk Information System or IRIS program), Office of Air and Radiation (including but not limited to the Office of Air Quality Planning & Standards), Office of Congressional and Intergovernmental Relations, Office of the Executive Secretariat, Office of Policy, Office of Public Affairs, Office of General Counsel, any EPA Regional Office, or Office of Enforcement and Compliance Assurance regarding or relating to:

- ethylene oxide and the Miscellaneous Organic Chemical Manufacturing ("MON") Rule,⁵ Ethylene Production Rule,⁶ the Ethylene Oxide Sterilization Rule, the Polyether Polyols Rule,⁷ the Synthetic Organic Chemical Manufacturing Rule (also known as the Hazardous Organic NESHAP),⁸ the National Emission Standards for Hazardous Air Pollutants (NESHAP) rule for any other ethylene oxide-emitting source category, or any individual source in any of these source categories;⁹ or
- Fenceline monitoring of the ambient air and any of the above listed rules.

Third, please provide any and all documents and communications, subsequent to July 1, 2019, regarding (1) any of the above-listed rules and (2) either ethylene oxide or fenceline monitoring, between any of the above listed components of EPA and:

- TCEQ, including but not limited to Michael Honeycutt and any other TCEQ staff or any person or organization contracting with or otherwise affiliated with TCEQ, or

⁵ Miscellaneous Organic Chemical Manufacturing Risk and Technology Review, <https://www.epa.gov/stationary-sources-air-pollution/miscellaneous-organic-chemical-manufacturing-national-emission> (final rule published Aug. 12, 2020).

⁶ Ethylene Production Risk and Technology Review, <https://www.epa.gov/stationary-sources-air-pollution/acetal-resins-acrylic-modacrylic-fibers-carbon-black-hydrogen> (final rule published July 6, 2020).

⁷ Polyether Polyols Production: National Emission Standards for Hazardous Air Pollutants, <https://www.epa.gov/stationary-sources-air-pollution/polyether-polyols-production-national-emission-standards-hazardous> (final rule published Mar. 27, 2014).

⁸ Synthetic Organic Chemical Manufacturing Industry: Organic National Emission Standards for Hazardous Air Pollutants, <https://www.epa.gov/stationary-sources-air-pollution/synthetic-organic-chemical-manufacturing-industry-organic-national> (final rule published Dec. 12, 2006).

⁹ Ethylene Oxide Emissions Standards for Sterilization Facilities: National Emission Standards for Hazardous Air Pollutants, <https://www.epa.gov/stationary-sources-air-pollution/ethylene-oxide-emissions-standards-sterilization-facilities> (proposed information collection request dated June 5, 2020).

- Any private industry or trade association, for-profit corporation, or any of its representatives, including but not limited to the American Chemistry Council, the Ethylene Oxide Sterilization Association, Exponent, TERA, or Ramboll.

Please do not include any records that have already been placed in a regulations.gov docket; instead, for any such documents (not already cited above), please provide a list with each specific full web link with the full document ID number.

It may be possible for us to further limit this request if we have a better idea of the nature and scope of the records in your files. Please contact Earthjustice to discuss this possibility. In addition, to the extent that records responsive to this request are available in a widely-used electronic format (*e.g.*, pdf, Excel, Word, or WordPerfect files), we would prefer to receive them in that format, provided that the electronic versions are in comprehensible form.

If you regard any of the requested records to be exempt from required disclosure under FOIA, we request that you disclose them nevertheless, as such disclosure would serve the public interest of educating the public, and advancing the purposes of the Clean Air Act. In the event that any requested document is claimed, or continues to be claimed, exempt from disclosure or review, or otherwise withheld, we request an index or log of documents withheld, with the maximum possible identifying information that you can provide, including a description of the document withheld, its date, its location, its recipient(s) and the specific reason(s) the document is being withheld. 5 U.S.C. § 552(b).

We also request that responsive records be released as soon as they are available, on a rolling basis, but in no event later than 20 days, as required by law. To the extent that some subset of the requested records is readily available and can be provided immediately, please send it immediately while EPA searches for other records.

Definitions

For the purposes of this request, the terms “record” and “records” mean all materials in whatever form (handwritten, typed, electronic or otherwise produced, reproduced, or stored) in EPA’s possession since July 1, 2019, including, but not limited to, letters, memoranda, correspondence, notes, applications, completed forms, studies, reports, reviews, guidance documents, policies, notes of telephone conversations, telefaxes, e-mails, text messages, internet chat logs, documents, databases, drawings, graphs, charts, photographs, minutes of meetings, electronic and magnetic recordings of meetings, and any other compilation of data from which information can be obtained. Without limitation, the records requested include records relating to the topics described above at any stage of development, whether proposed, draft, pending, interim, final, embargoed, or otherwise. All of the foregoing are included in this request if they are in the possession of or otherwise under the control of the EPA or any of its offices nationwide, including responsive records in or on the personal computers, cellphones, or other devices, or personal email accounts used by any federal employee or official if used for any governmental purpose.

Exempt Records

If you regard any of the requested records to be exempt from required disclosure under FOIA, we request that you disclose them nevertheless, as such disclosure would serve the public interest of educating citizens and advancing the purposes of the Clean Air Act. Should you nonetheless invoke a FOIA exemption with regard to any of the requested records, please include in your full or partial denial letter sufficient information for the Sierra Club to appeal the denial. To comply with legal requirements, the following information must be included:

1. Basic factual material about each withheld item, including the type of document; the originator, or for emails, the sender and the recipient; the date; the length of the document; the general subject matter, including for emails the subject line; and the location of each item; and
2. Explanations and justifications for denial, including the identification of the category within the governing statutory provision under which the document (or portion thereof) was withheld and a full explanation of how each exemption fits the withheld material.

If you determine that portions of a record requested are exempt from disclosure, please redact the exempt portions and provide the remainder of the record to the Sierra Club at the address listed below. If the requested documents do not exist, please indicate that in your written response.

Fee Waiver Request

Pursuant to 5 U.S.C. § 552(a)(4)(A)(iii), Sierra Club requests a fee waiver because “disclosure of the information is in the public interest because it is likely to contribute significantly to public understanding of the operations or activities of the government and is not primarily in the commercial interest of the requester.” 5 U.S.C. § 552(a)(4)(A)(iii); 40 C.F.R. § 2.107(l)(1). EPA examines four factors when considering whether a request contributes to public understanding: 1) the subject of the request; 2) the informative value of the information being disclosed; 3) the contribution to an understanding of the subject by the public is likely to result from disclosure; and 4) the significance of the contribution to public understanding. *See* 40 C.F.R. § 2.107(l)(2). Additionally, to determine whether the request “is not primarily in the commercial interest of the requester” the government will consider two factors: 1) the existence and magnitude of a commercial interest, and 2) the primary interest in disclosure. *See id.* § 2.107(l)(3).

As demonstrated below, each of the factors related to the fee waiver requirements specified in EPA’s FOIA regulations at 40 C.F.R. § 2.107(l)(2)–(3), weigh in favor of granting Sierra Club’s fee waiver request. Moreover, federal courts have held that FOIA “is to be liberally construed in favor of waivers for noncommercial requesters.” *Citizens for Responsibility & Ethics in Washington v. U.S. Dep’t of Health & Human Servs.*, 481 F. Supp. 2d 99, 106 (D.D.C.

2006) (quoting *McClellan Ecological Seepage Situation v. Carlucci*, 835 F.2d 1282, 1284 (9th Cir. 1987)).

The Request is in the Public Interest.

Factor 1: The Request Seeks Information That Has a “Direct and Clear” Connection to Operations or Activities of the Federal Government.

Sierra Club’s request focuses on and thus plainly concerns information regarding the operations and activities of the federal government. It seeks information regarding communications about scientific and health-related information on a chemical, ethylene oxide, that the EPA has a legal responsibility to regulate to protect public health and the environment under the Clean Air Act and other statutes. The Department of Justice Freedom of Information Act Guide expressly concedes that “in most cases records possessed by federal agency will meet this threshold” of identifiable operations or activities of the government.¹⁰ Records requested are directly and clearly related to EPA’s regulation of this chemical as a hazardous air pollutant, and its operations and activities to create and evaluate scientific, toxicological, and health-related information.

Factor 2: Disclosure of the Requested Records is “Likely to Contribute” to Public Understanding of Government Operations or Activities.

Ethylene oxide is a flammable, colorless gas and is a known carcinogen and neurotoxicant that can also cause acute health impacts to the eyes, skin, nose, throat and lungs.¹¹ After years of evaluation and a scientifically sound, multi-step, external peer-reviewed and public comment process, in December 2016, EPA completed a toxicological evaluation of the chemical ethylene oxide.¹² EPA scientists in the IRIS program updated the health reference value for cancer risks from ethylene oxide recognizing that it is far more carcinogenic than previously understood.¹³

EPA determined that the “full lifetime unit risk estimate” including age-dependent adjustment factors due to early-life exposure, is 5.0×10^{-3} or 0.005 per $\mu\text{g}/\text{m}^3$, and also provided additional adult exposure-only unit risk estimates for certain kinds of cancer incidences.¹⁴ IRIS

¹⁰ DOJ Fees and Fee Waivers at 27,
<https://www.justice.gov/sites/default/files/oip/legacy/2014/07/23/fees-feewaivers.pdf#p22>.

¹¹ EPA, IRIS, Ethylene Oxide (last updated July 28, 2017),
https://cfpub.epa.gov/ncea/iris2/chemicalLanding.cfm?substance_nmbr=1025.

¹² *Id.*

¹³ EPA IRIS, *Evaluation of the Inhalation Carcinogenicity of Ethylene Oxide* (Dec. 2016),
https://cfpub.epa.gov/ncea/iris/iris_documents/documents/toxreviews/1025tr.pdf.

¹⁴ EPA, *Evaluation of the Inhalation Carcinogenicity of Ethylene Oxide, Executive Summary* at 8 (Dec. 2016),
https://cfpub.epa.gov/ncea/iris/iris_documents/documents/subst/1025_summary.pdf.

determined that EPA has “relatively high” confidence in the unit risk estimate, “based on strong epidemiological evidence supplemented by other lines of evidence,” including “a large, high-quality epidemiology study with individual worker exposure estimates,” and found that the method of linear low-exposure extrapolation used “is strongly supported,” and that “[c]onfidence . . . is particularly high for the breast cancer component,” based on “over 200 incident cases.”¹⁵

Ethylene oxide is a listed hazardous air pollutant EPA has a legal duty and responsibility under the Clean Air Act, 42 U.S.C. § 7412, to regulate and restrict in order to protect public health and the environment. In 2018, EPA identified this chemical “as a potential concern in several areas across the country,” due to cancer risk at levels the agency deems presumptively unacceptable, as part of the 2014 National Air Toxics Assessment (NATA).¹⁶ Consequently, EPA has committed to “review Clean Air Act regulations for facilities that emit ethylene oxide to ensure that they protect the public.”¹⁷

The EPA Office of Inspector General is also conducting a review of these EPA rulemakings to evaluate “whether the EPA’s residual RTR process has sufficiently identified and addressed any elevated cancer risks from air toxics emitted by facilities.”¹⁸ While this review is ongoing, the EPA Office of Inspector General has called for prompt action from EPA to inform residents living near ethylene oxide-emitting facilities about the health concerns—most recently elevating this issue due to EPA’s inadequate response.¹⁹

In recent rulemakings, EPA has applied the 2016 IRIS value for ethylene oxide as the best available science on the cancer-causing effects of this chemical. *See, e.g.*, Miscellaneous Organic Chemical Manufacturing, 85 Fed. Reg. 49,084 (Aug. 12, 2020); Ethylene Production, 85 Fed. Reg. 40,386 (July 6, 2020); Stationary Combustion Turbines, 85 Fed. Reg. 13,524 (Mar. 9, 2020). In the rulemakings for Hydrochloric Acid Production and the Miscellaneous Organic Chemical Manufacturing Rule, however, EPA also requested public comment on whether this

¹⁵ *Id.* at 5-6.

¹⁶ EPA, 2014 NATA: Assessment Results (last updated Aug. 27, 2018), <https://www.epa.gov/national-air-toxics-assessment/2014-nata-assessment-results>.

¹⁷ EPA, Fact Sheet: EPA Taking Steps to Address Emissions of Ethylene Oxide (2018), <https://www.epa.gov/hazardous-air-pollutants-ethylene-oxide/fact-sheet-epa-taking-steps-address-emissions-ethylene-oxide>.

¹⁸ EPA, OIG, Project Notification: EPA Actions to Address Air Toxics Emissions Through Its Residual Risk and Technology Review Program, Project No. OA&E-FY19-0091 (Dec. 17, 2018), <https://www.epa.gov/office-inspector-general/notification-epa-actions-address-air-toxics-emissions-through-its-residual>.

¹⁹ EPA, OIG, Management Alert: Prompt Action Needed to Inform Residents Living Near Ethylene Oxide-Emitting Facilities About Health Concerns and Actions to Address Those Concerns (Mar. 31, 2020), https://www.epa.gov/sites/production/files/2020-03/documents/epaoig_20200331-20-n-0128_glance.pdf; *see also* https://www.epa.gov/sites/production/files/2020-08/documents/epaoig_20-n-0128_ig_comment_on_response.pdf.

value should be used “for regulatory purposes.” EPA, Proposed Rule, HCl Production, 84 Fed. Reg. 1570, 1584 (Feb. 4, 2019); 84 Fed. Reg. 69,187, 69,218 (Dec. 17, 2019). In each instance, Sierra Club and other commenters have strongly supported EPA’s use of the 2016 IRIS value as the best available science.²⁰

In April 2019, TCEQ announced through submission of a public comment to EPA that it plans to reject EPA’s IRIS value and create its own, different “unit risk factor” or “URF” for ethylene oxide.²¹ TCEQ stated that it is “in the process of deriving a URF for ethylene oxide based on the same underlying data as is used by EPA.”²² TCEQ submitted its draft factor to the EPA as part of the Miscellaneous Organic Chemical Manufacturing (MON) rulemaking. Miscellaneous Organic Chemical Manufacturing, 85 Fed. Reg. 49,084, 49,098 (Aug. 12, 2020).

Ethylene oxide is relevant to a number of recent and ongoing rulemakings, and EPA has indicated it will take final action regarding industry’s request for correction of the National Air Toxics Assessment in regard to the risk factor for ethylene oxide in the near future. 85 Fed. Reg. at 49,098. However, there is currently little or no information publicly available regarding EPA staff’s consideration or use of information created by TCEQ, or EPA’s role in working or coordinating with TCEQ or other outside parties, and vice versa, since TCEQ proposed its risk value in late June, 2019. Thus, the records requested will contribute to the public understanding of EPA’s “operations and activities” associated with this critically important information.

The Freedom of Information Act Guide makes it clear that, in the Department of Justice’s view, the “likely to contribute” determination hinges in substantial part on whether the requested documents provide information that is not already in the public domain. The requested records are “likely to contribute” to an understanding of EPA’s decisions because they are not otherwise in the public domain and are not accessible other than through a FOIA request.

The information that the Sierra Club seeks will significantly contribute to the public’s understanding of EPA’s implementation of the Clean Air Act’s requirements for the control of hazardous air pollutants, and EPA’s sharing of scientific data or information with, coordination with, or assistance to a state regarding EPA’s evaluation and use of the science on such pollutants. This information will facilitate meaningful public participation, review, and contributions to EPA’s rulemaking processes and any other potential public comment opportunities regarding EPA’s use of the IRIS value, therefore fulfilling the requirement that the

²⁰ Comments of Sierra Club *et al.*, EPA Proposed Rule, Stationary Combustion Turbines (May 28, 2019), <https://www.regulations.gov/document?D=EPA-HQ-OAR-2017-0688-0103>; Comments of Sierra Club *et al.*, EPA, Proposed Rule, Hydrochloric Acid Production (Apr. 26, 2019), <https://www.regulations.gov/document?D=EPA-HQ-OAR-2018-0417-0147>.

²¹ TCEQ Comment, submitted by Toby Baker, Exec. Dir., TCEQ, to EPA Sector Policies & Programs Div., OAQPS, Docket ID No. EPA-HQ-OAR-2018-0417 (Apr. 26, 2019), <https://www.regulations.gov/document?D=EPA-HQ-OAR-2018-0417-0142>.

²² *Id.* at 2.

documents requested be “meaningfully informative” and “likely to contribute” to an understanding of the agency’s decision-making process.

Factor 3: Disclosure of the Requested Records Will Contribute to “Public Understanding” of EPA’s Implementation of the Clean Air Act’s Requirements for Hazardous Air Pollutants.

The Sierra Club has demonstrated involvement in clean air issues, particularly on hazardous air pollutants such as ethylene oxide, for decades. Most recently, Sierra Club has reviewed and disseminated information to other concerned members of the public, and has submitted comments into each of the dockets where the issue of ethylene oxide has come up so far in 2019 and in 2020. The Sierra Club also unquestionably has the “specialized knowledge” and “ability and intention” to broadly disseminate the information requested in a manner that contributes to the understanding of the “public-at-large.” Sierra Club disseminates the information it receives through FOIA requests in a variety of ways, including, but not limited to: analysis and distribution to the media, distribution through publication and mailing, posting on the Club’s website, emailing and listserv distribution to its members and supporters across the U.S., and via public meetings and events. Every year the Sierra Club website receives roughly 40,730 unique visits and 100,381 page views; on average, the site gets 104 visits per day. *Sierra Magazine*, which is a quarterly magazine published by the Sierra Club, has a circulation of approximately 1,000,000. *Sierra Club Insider*, an electronic newsletter, is sent to over 850,000 people twice a month. In addition, Sierra Club disseminates information obtained by FOIA requests through comments to administrative agencies, and where necessary, through the judicial system.

Sierra Club’s detailed description of its capacity and will to disseminate information gathered from the requested records demonstrates that disclosure of the records will contribute to public understanding. *See, e.g., Judicial Watch v. Rossotti*, 326 F.3d 1309, 1314 (D.C. Cir. 2003) (requester demonstrates likelihood of contributing to public understanding of government operations and activities where it specifies multiple channels for disseminating information and estimated viewership numbers).

Factor 4: Disclosure of the Requested Records Will Make a “Significant” Contribution to the Public’s Understanding of EPA’s Implementation of the Clean Air Act’s Requirements for Hazardous Air Pollutants.

The fourth factor EPA considers is whether the records are “likely to contribute ‘significantly’ to public understanding of government operations or activities.” 40 C.F.R. § 2.107(l)(2)(iv); *see also Fed. CURE v. Lappin*, 602 F. Supp. 2d 197, 205 (D.D.C. 2009) (the relevant test is whether public understanding will be increased after disclosure, as opposed to the public’s understanding prior to the disclosure). Where information is not currently available to the general public, and where “dissemination of information . . . will enhance the public’s understanding,” the fourth public interest factor is satisfied. *Fed. CURE*, 602 F. Supp. 2d at 205.

Here, the request satisfies the fourth factor. As documented above, the public has little to no knowledge of the information of EPA's coordination with TCEQ or other outside parties, and vice versa, on ethylene oxide since TCEQ's risk value was proposed, even though this may affect various EPA scientific, policy, or regulatory decisions, or the public health.

Further, the subject of the request concerns the operations and activities of the federal government, including its development of scientific information, scientific policy, and regulations, about which the public has a right to know.

The proper functioning of government depends on transparency, and requestors should not have to file lawsuits to motivate EPA to fulfill its obligations under FOIA. As a practical matter, the public has little or no information regarding EPA's consideration of the 2016 IRIS value, the process it is undertaking to evaluate information that TCEQ or outside parties have provided, or how EPA and such parties are sharing information regarding updates, creation, or use of current or new information on ethylene oxide as relevant to the public and to various agency regulations since the TCEQ value was proposed.

Receiving the requested information would significantly contribute to the public's understanding of whether and how EPA is following the best available science, whether EPA is freely and equitably sharing information among interested members of the public regarding dangerous chemicals such as ethylene oxide, and whether EPA is implementing the Clean Air Act's requirements for hazardous air pollutants in a lawful way or whether it is attempting to ignore its own scientific policies, protocols, guidance, and staff scientists' recommendations. This information would contribute significantly to the public's understanding of EPA's use of available science and sharing of such science for regulatory and other decisions. Further, it would contribute significantly to the public's evaluation of EPA's use of science and proposed and final regulations on which the public has a right to public notice-and-comment under the Clean Air Act.

There is no Commercial Interest in Disclosure of the Requested Records.

The Sierra Club has no commercial interest in the requested records. Nor does the Sierra Club have any intention to use these records in any manner that "furthers a commercial, trade, or profit interest" as those terms are commonly understood. The Sierra Club is a nonprofit, tax-exempt organization under section 501(c)(4) of the Internal Revenue Code, and as such has no commercial interest. The requested records will be used for the furtherance of Sierra Club's mission to inform the public on matters of vital importance to the environment and public health.

* * *

Therefore, we respectfully request, because the public will be the primary beneficiary of this requested information, that EPA waive processing and copying fees pursuant to 5 U.S.C. § 552(a)(4)(A)(iii). In the event that your agency denies a fee waiver, please send a written

explanation for the denial. If you deny our request for a fee waiver, please provide an estimate of all charges for supplying the records Sierra Club has requested in advance and allow me to respond to the estimate before proceeding with fulfilling the request.

Record Delivery

We prefer to receive the records in **searchable and analyzable electronic format wherever possible**. We request that EPA comply with all relevant deadlines and other obligations set forth in FOIA and the agency's regulations. 5 U.S.C. § 552, *id.* § 552(a)(6)(A)(i); 40 C.F.R. § 2.104. This includes the requirement that a response to this request must be made within 20 working days of your receipt of this letter.

Please mail or email copies of all requested records as soon as possible to us at the email addresses in the signature block below. **Please produce them on a rolling basis**; at no point should the search for—or deliberation concerning—certain records delay the production of others that the agency has already retrieved and elected to produce. If EPA concludes that any of the records requested here are publicly available, please let me know.

Thank you for your cooperation. If you find that this request is unclear or could potentially be narrowed in any way, please do not hesitate to contact us or Robyn Winz, Earthjustice Litigation Paralegal (rwinz@earthjustice.org) to see if we can clarify the request or otherwise expedite and simplify your efforts to comply.

Sincerely,



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Submitted on behalf of:
SIERRA CLUB

Neil Carman